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CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 17.8
TITLE: REQUIREMENTS FOR FDA (FOOD AND DRUG ADMINISTRATION) APPROVAL FOR MEDICAL DEVICES

AUTHORITY: 38 CFR 17.270(a) and 17.272(a)

RELATED AUTHORITY: 32 CFR 199.2(b) and 199.4(a), (b), (c), and (g)(15)

I. EFFECTIVE DATE

A. Devices used for an FDA (Food and Drug Administration) approved application - effective date is the date of the FDA approval.

B. Device used for a non-FDA approved application - effective date is the date the reliable evidence supports the application is safe, effective, and in accordance with nationally accepted standards of practice in the medical community.

C. Category-B IDE (Investigational Device Exemption) - effective date is the date the device is classified as a Category-B device by the FDA.

II. DESCRIPTION

A. Section 201(h) of the Food, Drug and Cosmetic Act (codified as Title 21 United States Code, Chapter 9, subchapter II, subsection 321(h)) defines medical devices as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them.

2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.

3. Intended to affect the structure of any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not

dependent upon being metabolized for the achievement of any of its primary intended purposes.

B. Devices that meet this definition are regulated by the FDA and are subject to premarketing and postmarketing regulatory controls. (For further information see the FDA's web site: http://www.fda.gov.)

C. The FDA places all medical devices into one of three classes. The class dictates the degree of regulatory control needed to assure safety and effectiveness of the device. The three classes are addressed below:

1. Class I - Devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness. Examples of Class I devices are enema kits, elastic bandages, and pipetting.

2. Class II - Devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness. Examples of Class II devices include power wheelchairs and pregnancy test kits.

3. Class III - Devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval. Examples of Class III devices include implantable pacemaker pulse generators, automated heparin analysers, and infant radiant warmers.

D. The following are the two main routes to the market for a new device. If the manufacturer can establish substantial equivalence, premarketing notification (510(k)) approval is all that is required. Otherwise, full premarketing testing and approval are required. The premarketing approval process is lengthy since it requires review and analysis of all completed studies, trials and literature:

1. Premarket notification is also known as a "510(k) submission," since the basic requirement for it is in Section 510(k) of the Federal Food, Drug, and Cosmetic Act. Premarket notification must be submitted at least 90 days before the manufacturer anticipates marketing the device. The reason for notifying FDA that a device is about to be marketed is to let FDA determine whether or not the device is substantially equivalent to one already in commercial distribution. If the FDA determines that the device is substantially equivalent, the manufacture is free to market it.

2. According to the FDA, the term "substantially equivalent" is not intended to be so narrow as to refer to devices, which are identical to marketed devices nor so broad as to refer to devices that are intended to be used for the same purposes as marketed products. The term is to be constructed narrowly where necessary to assure

the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to the safety and effectiveness.

III. POLICY

A. Medical devices may be covered when medically necessary, appropriate, the standard of care, and not otherwise excluded.

B. Medical devices must be FDA-approved. Not all FDA-approved devices are covered. Coverage of a medical device is subject to all other requirements of the law, rules, and policy governing CHAMPVA. If the device is used for a noncovered or excluded indication, benefits may not be allowed. For example, tinnitus masker is an FDA-approved device; however, CHAMPVA considers this device unproven and, therefore, not a benefit.

C. Use of FDA-approved devices for off-label or non-approved FDA applications may be covered if documented by reliable evidence as safe, effective, and in accordance with nationally accepted standards of practice in the medical community. Coverage is subject to all other requirements of the law, rules, and policy governing CHAMPVA. (Refer to Chapter 2, Section 22.1, *Pharmacy*, for information regarding hierarchy of reliable evidence.)

D. A humanitarian use device approved for marketing through a Humanitarian Device Exemption application may be covered. Coverage of any such device is subject to all other requirements of the law, rules, and policy governing CHAMPVA.

E. Devices with a FDA-approved IDE categorized by the FDA as non-experimental/investigational (FDA Category-B), which was the subject of an FDA approved clinical trial(s), may be considered for coverage once it receives FDA approval for commercial marketing. Coverage is dependent on the device meeting the FDA requirements/conditions of approval and all other requirements governing CHAMPVA.

IV. EXCLUSIONS

A. Experimental/Investigational (Category-A) IDEs. Refer to Chapter 2, Section 16.5, *Investigational or Experimental (Unproven) Procedures*, for guidance regarding the handling of claims for services or supplies related to experimental or investigational (unproven) devices, treatment, and procedures.

B. Off-label or non-approved FDA applications that are not documented as safe, effective and in accordance with nationally accepted standards of practice in the medical community.

END OF POLICY